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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,844	02/01/2000	ANGELA VERONICA FLANNERY	PM1265461	6871

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,844

Applicant(s)

FLANNERY ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Response to Amendment

1. Claims 10, 11 and 17 have been amended and claim 22 has been cancelled as requested in the amendment of Paper No. 16, filed on May 30, 2002. Claims 10-12 and 17 are pending in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on May 30, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 10-12, 17 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in section 11 of Paper No.16. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

Applicant submits that the utility of the claimed ZGGBP1 is based on sequence similarity to known proteins, specifically "SEQ ID NO:2 has high homology to the human and mouse forms of NEDD-4" (page 14, third paragraph of the Response). Applicant refers to the tables presented in Exhibits 1-3 to show the level of degree of sequence similarity. Applicant further

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refers to the Revised Interim Utility Guidelines Training Materials, which states that "if there is a well-established utility already associated with the claimed invention, the utility need not be asserted in the specification as filed" (page 15, third paragraph of the Response). This has not been found to be persuasive for the following reasons.

According to the instant specification, ZGGBP1 gene "shows appreciable sequence homology to the ned-4 gene [which] is a human homologue of the mouse nedd-4 gene which is known to be differentially expressed during neural development and to be involved in signal transduction" (page 1, lines 28-32 of the instant specification). Analysis of the data provided in Exhibit 1 of the Response confirms that ZGGBP1 has 63% sequence identity to human NED4 and 77% sequence identity to mouse NED4. However, based on the analysis of the structural similarities one skilled in the art can, at best, only conclude that the instant ZGGBP1 and NED4 proteins belong to the same family, and it is well known in the art that members of the same protein family can have substantially diverse functions. Numerous publications exist on the topic that amino acid structure cannot necessarily predict the function of the protein: "Knowing the protein structure by itself is insufficient to annotate a number of functional classes and is also insufficient for annotating the specific details of protein function" (see Skolnick et al., Box 2 on page 36). Moreover, "Structural similarity does not necessarily mean a common evolutionary origin and homologous sequences may evolve into different folds (according to current classification schemes) (See Bork et al., Current Opinion in structural Biology, 1998, 8, page 332, first column, second paragraph).

Therefore, in the absence of knowledge of the biological significance of these specific ZGGBP1 polypeptides of SEQ ID NO:2 and 4 there is no immediately obvious patentable use

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for the claimed proteins. There is no evidence of record, which associates the instant polypeptides with any disease or disorder, or with any specific and credible biological activity. Applicant submits that "members of the NEDD4 family [...] have ubiquitin protein ligase activity", or "[are able] to interact with epithelial sodium channel", or "can bind to phosphoserine and phosphothreonine residues", or "may be able to interact with a larger repertoire of protein substrates than first thought" (page 15, second paragraph of the Response). There is little doubt that the members of NEDD4 family have biological significance and carry numerous physiological functions. However, the data based on functional studies of different domains of different members of NEDD4 family does not support specific substantial and credible utility of the NEDD4 family. Therefore, sequence similarity to the family of proteins that exhibit many different biological activities does not provide evidence for identification of a substantial credible and specific utility of the instant claimed sequences. There is no evidence of record that would disclose that polypeptides of SEQ ID NO:2 or 4 have any of the activities of NEDD4 family. One skilled in the art would not expect that administration of the claimed polypeptides would have any effect on an individual because there is no evidence provided in the instant specification to suggest otherwise.

Thus, since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 10-12, 17 are also rejected under 35 U.S.C. 112, first paragraph for the reasons of record in section 12 of Paper No.16.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
August 1, 2002

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JOHN LUM
PRR. 10/1/02
OWNER